

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of
SAINT-LEGER.

Serial No. 09/449,924

Filed on : December 2, 1999

Group Art Unit : 1615

Examiner : Pulliam, A

For : « **COSMETIC OR DERMATOLOGICAL COMPOSITION COMPRISING
AT LEAST ONE ALKYNYL CARBAMATE AND AT LEAST ONE POLYOL** »



DECLARATION PURSUANT TO 37 CFR 1.132

I, Géraldine LEREBOUR, declare,

That I am a French citizen residing 6, résidence des haies, 78350 LES LOGES EN JOSAS, FRANCE.

That I have been awarded a DESS of microbiology applied to pharmaceutical, food and cosmetic products.

That I have been employed as a Research Chemical Engineer in the Research Laboratories of L'OREAL since March 1, 1999.

That I have read and I am familiar with the invention set forth in United States Patent Application 09/449,924 filed on December 2, 1999 for « **COSMETIC OR DERMATOLOGICAL COMPOSITION COMPRISING AT LEAST ONE ALKYNYL CARBAMATE AND AT LEAST ONE POLYOL** ».

That I am familiar with the references cited and more particularly with Blieszner et al. (WO 96/24329) and Merianos (US 5,552,425).

That I compared the activity against several microorganisms of a composition according to the invention to the activity against the same microorganisms of compositions according to Blieszner et al. (WO 96/24329) and Merianos (US 5,552,425).

COMPOSITIONS TESTED**COMPOSITION A ACCORDING TO SN 09/449,924**

• Acrylic acid / alkyl acrylates crosspolymer	0.9g
• Sodium hydroxide	0.35g
• 3-iodo-2-propynyl butylcarbamate (IPBC)	0.012g
• 3-(2-ethylhexyloxy)-1,2-propanediol	0.1g
• Water	q.s. 100g

COMPOSITION B ACCORDING TO WO 96/24329 OR US 5,552,425

• Acrylic acid / alkyl acrylates crosspolymer	0.9g
• Sodium hydroxide	0.35g
• 3-iodo-2-propynyl butylcarbamate (IPBC)	0.012g
• propylene glycol	0.1g
• Water	q.s. 100g

COMPOSITION C ACCORDING TO WO 96/24329 OR US 5,552,425

• Acrylic acid / alkyl acrylates crosspolymer	0.9g
• Sodium hydroxide	0.35g
• 3-iodo-2-propynyl butylcarbamate (IPBC)	0.012g
• butylene glycol	0.1g
• Water	q.s. 100g

COMPOSITION D ACCORDING TO WO 96/24329

• Acrylic acid / alkyl acrylates crosspolymer	0.9g
• Sodium hydroxide	0.35g
• 3-iodo-2-propynyl butylcarbamate (IPBC)	0.012g
• hexylene glycol	0.1g
• Water	q.s. 100g

The 3-iodo-2-propynyl butyl carbamate (IPBC) used in the tested compositions is the product sold under the denomination GLYCACIL L® by the firm LONZA, containing 10% IPBC, and used at a concentration of 0.12%.

TESTS CARRIED OUT

One week before the test, the microbial strain is introduced into a malt containing gelose and is then incubated in an oven at 35°C.

The day of the test, 20g of a composition containing the compounds to be tested are put in a sterile pillbox. 1% of a microbial suspension including 10^8 germs per ml is inoculated into said composition. Thus, a concentration of 10^6 germs is obtained in the composition. The contaminated sample is incubated in a oven at 22°C.

After 7 days of incubation, decimal dilutions of 1g of the composition in the broth Eugon LT100 are carried out and spread out on the surface of Petri dishes containing Eugon LT100 gelose.

Then, the colonies are counted on the dishes containing more than 20 and less than 200 colonies.

I obtained the following results : (number of germs after an incubation during 7 days)

Composition	<i>Escherichia coli</i>	<i>Pseudomonas aeruginosa</i>	<i>Enterococcus faecalis</i>	<i>Candida albicans</i>
A	< 200	$8,6 \cdot 10^4$	$1,5 \cdot 10^5$	< 200
B	$2,8 \cdot 10^4$	$1,6 \cdot 10^7$	$2,1 \cdot 10^6$	$2,1 \cdot 10^6$
C	$6,8 \cdot 10^5$	$1,6 \cdot 10^7$	$1,8 \cdot 10^6$	$2,3 \cdot 10^5$
D	$7,9 \cdot 10^4$	$1,2 \cdot 10^7$	$2,2 \cdot 10^6$	$1,4 \cdot 10^6$

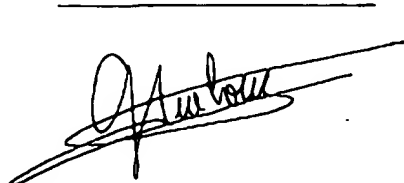
< 200 means that the lower limits of sensibility of the process do not allow anymore to count the germs.

It appears from the above results that the combination (A) of 3-iodo-2-propynyl butylcarbamate and 3-(2-ethylhexyloxy)-1,2-propanediol shows synergic antibacterial activity against *Escherichia coli*, *Pseudomonas aeruginosa*, *Enterococcus faecalis* and *Candida albicans*, by contrast with the prior art combinations (B, C and D).

Thus, the combination according to the invention provides a surprising and unexpected effect over the prior art combinations.

I further declare that all statements made herein of my own knowledge are true and that all statements are made on information and belief are believed to be true ; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date : 21 Novembre 2003

A handwritten signature in black ink, appearing to be 'J. A. ...', is written over a horizontal line.